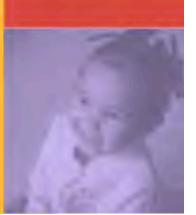


The National Children's Study

U.S. Department of Health and Human Services
National Institute of Child Health and Human Development
National Institute of Environmental Health Sciences
Centers for Disease Control and Prevention
U.S. Environmental Protection Agency



What Is the National Children's Study?



- The National Children's Study (Study) is the largest long-term study of children's health and development ever to be conducted in the U.S.
- *Longitudinal study*—meaning it will study the same group of children, their families, and their environment over an extended period of time (21 years or longer, from before birth)
- Study common range of “environmental” exposures and less common outcomes in 100,000 participants
- Examine genetic factors and expression
- Environment defined broadly—chemical, physical, behavioral, social, and cultural



Why Is the Study Important?

- Between 1980 and 1995, the percentage of children with asthma doubled
- The proportion of children aged 6–18 who were overweight increased from 6% in 1976–1980 to 15% in 1999–2000
- 3–8% of children born each year will be affected by a neurodevelopmental disorder
- Great disparities remain in infant mortality rates among ethnic groups

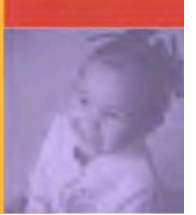


Why Conduct the Study Now?

- The Study is needed to identify effects or to assure safety
 - Children generally have an increased vulnerability to environmental exposures
 - Exposures to some agents have caused serious developmental effects (e.g., lead, alcohol)
 - There are known current exposures of high frequency (e.g., pesticides, phthalates)
- Longitudinal design will allow examination of multiple exposures and multiple outcomes
- Previous and existing studies have been limited in size and scope



Why Focus on Children?

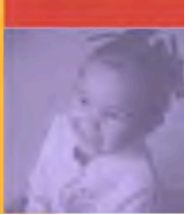


Children have:

- Increased vulnerability to environmental exposures
- Critical windows of vulnerability during development
- Immature mechanisms for detoxification and protection
- Differences in metabolism and behavior that may yield higher exposure in the same environments



What Will Be the Impact on Health and Research?



- The National Children's Study will identify not only what is harmful but what is helpful to children's health
- The data collected will become a national resource that has the potential to answer future questions that science has yet to ask



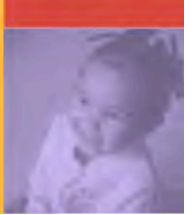
History of the National Children's Study



- President's Task Force on Environmental Health Risks and Safety Risks to Children (1998)
 - Charged with developing strategies to reduce risk of environmental exposures to children
 - Co-chaired by HHS Secretary and EPA Administrator
 - Additional members included seven cabinet officers and senior staff



History of the National Children's Study

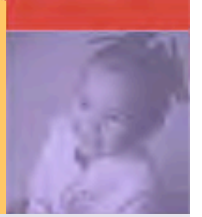


- Conclusions of President's Task Force
 - Many risks to children are not clear or quantified
 - Need for additional study of effects of environmental exposures
 - Consultation in January 2000 endorsed study: large, bold, multiple agencies, public-private partnerships
 - New money would be required to carry it out





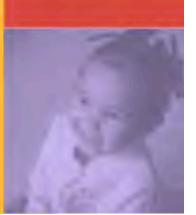
Public Law 106-310: Children's Health Act of 2000



- **(a) PURPOSE - ... to authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.**
- **(b) IN GENERAL -** The Director of NICHD shall establish a consortium of representatives from appropriate Federal agencies (including the CDC and EPA) to:
 - (1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
 - (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes...
- **(e) AUTHORIZATION OF APPROPRIATIONS -** There are authorized to be appropriated to carry out this section \$18,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2002 through 2005.



How Will the Study Be Conducted?



- Using a longitudinal, representative sample of the U.S.
- Using state-of-the-art technology – tracking, measurement, data management
- Manage through a cooperative consortium of multiple agencies (U.S. EPA, HHS – NIH, CDC)
- Access extensive public-private partnerships
- Develop a national resource for future studies



Associations and Interactions



What Will the Study Provide?

- **Data to address concerns about exposure** to potential toxicants during childhood
- The **power to determine harmful, harmless, or beneficial effects** of exposures
- **Causal factors for a number of diseases** and conditions of children
- Information on how **multiple causes** interact to result in **multiple outcomes**



What Will the Study Provide?

- Large sample size required to **apply knowledge of the human genome** to understand multifactoral genetic conditions
- Identification of early life **factors that contribute to many adult conditions**
- A **national resource to answer future questions** by using stored biological and environmental samples and the extensive data for decades to come



Projected Timeline (as of March 2007)



2000–present	Pilot studies/methods development
2004	Developed Study Design and Study Plan
2005–2007	Start-up phase for Vanguard Centers, Coordinating Center
2007	Completion of the Study protocol
2007–2008	Protocol reviews and approvals
2007	Post Request for Proposals for additional Study Centers
2007	Award additional Study Centers
2007	Begin the Study at Vanguard Centers
2007–2008	Start-up phase for additional Study Centers
2009–2012*	Begin the Study at additional Study Centers
2009–2010*	First Study results become available
2013–2034*	Data analysis; publish results; public-use datasets

* PENDING FUNDING FOR FY 08



Study Funding (as of March 2007)



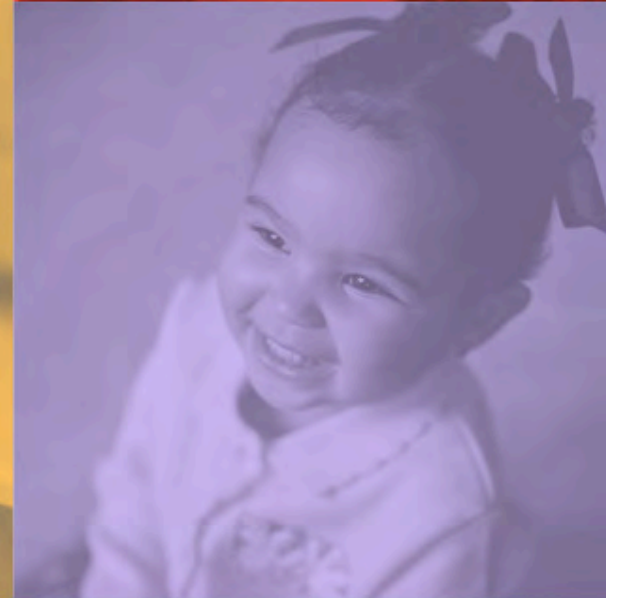
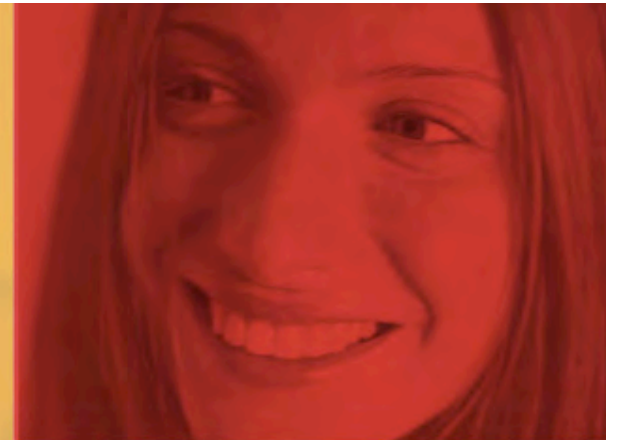
- **FY 00–06: ~\$50m from existing budgets of NICHD/EPA/CDC/NIEHS**
 - Infrastructure: Study Plan; Coordinating Center and 7 Vanguard Study Centers...
 - Scientific development: 28 workshops, 20 scientific reviews, 16 pilot studies; hypotheses, exposure and outcome measures, protocol in progress...
- **FY 07: \$69m appropriated by Congress to implement the Study**
 - To start 15–20 new Study Centers in 30 communities
 - To begin recruitment and prepare for enrollment of participants in the Vanguard Centers
- **No National Children's Study funding in the President's FY 08 budget**
- **To conduct the full Study: FY 08–34**
 - ~ \$120m/year for 26 years



Contact Information

- Check the Web site:
www.nationalchildrensstudy.gov
- Join the listserv for news and communication
(via the Web site)
- Contact us at NCS@mail.nih.gov





The End